REMARKS/ARGUMENTS

Claims 17-57 are pending in this Application. The Office Action mailed on December 6, 2006 included the following rejections:

1. Claims 17-52 were rejected under 35 U.S.C. § 112 first paragraph.
2. Claims 17-52 were rejected under 35 U.S.C. § 112 first paragraph.
3. Claims 25-33, 37, 41-47 and 53-57 are rejected under 35 U.S.C. 112 Second paragraph.
4. Claims 17, 19-47 and 49-57 stand rejected under the nonstatutory, judicially created doctrine of double patenting.
5. Claims 17, 19-47 and 49-57 stand rejected under the nonstatutory, judicially created doctrine of double patenting.

Applicant respectfully addresses the basis for each of the Examiner's rejections below.

Claims 17-52 are rejected under 35 U.S.C. 112 first paragraph as failing to comply with the enablement requirement.

The Action rejects claims 17-52 under 35 U.S.C. § 112 first paragraph, which states:

> The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims as amended specify a method for treating a patient in need of treatment for a cardiac disorder, by administering to said patient an effective amount of a **n-heptanoic acid** composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy. The specification states that the nutritional supplements or pharmaceutical preparations having seven-carbon fatty acids are useful in treatment of inherited metabolic disorders as well as acquired metabolic derangements, e.g., see [0069]. The specification provides an example as a preferred seven-carbon fatty acid is n-heptanoic acid, see [0070]. Applicant submits that the specification as filed full complies with 35 U.S.C. § 112 first paragraph. A specification that contains a teaching of the manner and process of making and

using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph.

Specifically, the present invention provides a method for treating a patient in need of treatment for a cardiac disorder, by administering to said patient an effective amount of a **n-heptanoic acid** composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy. The specification as filed provides specific guidance to the Fatty acid composition that may be used in the present invention. For example:

> **[0070]** A preferred seven-carbon fatty acid is n-heptanoic acid. n-Heptanoic acid is a saturated straight chain seven-carbon fatty acid with the following structure:
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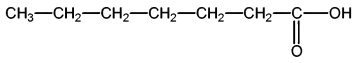
> 
>
> Triheptanoin is a triglyceride made by the esterification of three n-heptanoic acid molecules and glycerol. In regard to therapy, the terms heptanoic acid, heptanoate, and triheptanoin may be used interchangeably in the following description.

In addition, the specification provides specific guidance as to the specific heptanoate compositions that may be used. As seen in [0074] of the specification as filed.

> [**0074**] Unsaturated heptanoates can also be utilized as a nutritional supplement to overcome fatty acid metabolism deficiencies. In addition, substituted, unsaturated, and/or branched seven-carbon fatty acids which readily enter the mitochondrion without special transport enzymes can be utilized in the present invention. For example, 4-methylhexanoate, 4-methylhexenoate, and 3-hydroxy-4-methylhexanoate are broken down by normal β-oxidation to 2-methylbutyric acid with final degradation accomplished via the isoleucine pathway. Likewise, 5-methylhexanoate, 5-methylhexenoate, and 3-hydroxy-5-methylhexanoate are broken down by normal β-oxidation to isovaleric acid with final degradation accomplished via the leucine pathway.

In addition, the specification provides specific guidance as to the use of the specific heptanoate compositions for treatments, as seen in [0077] of the specification as filed:

> [0077] For patients suffering from a complete breakdown of the fatty acid metabolic pathway due to an inborn error of metabolism, triheptanoin is utilized at a concentration which provides approximately 15% to 40%, preferably 20% to 35%, and most preferably approximately 25% of the total calories per 24 hours.

As such, the specification satisfies the enablement requirement under 35 U.S.C. § 112. For the reasons mentioned above, the Applicants respectfully request the Examiner withdraw the rejection under 35 U.S.C. § 112.

Claim Rejections – Claims 25-33, 37, 41-47 and 53-57 are rejected under 35 U.S.C. 112 Second paragraph.

The Action rejects claims 25-33, 37, 41-47 and 53-57 under 35 U.S.C. 112 Second paragraph. Specifically stating that the use of "even carbon fatty acid metabolic pathway" is confusing as the n-heptanoic acid is not an even carbon fatty acid. The claim has been amended to read the method of any of Claims 17, 19, 20, 21, or 22, wherein said cardiac disorder comprises a reduced efficiency of a metabolic pathway of heart tissue. The present invention provides a method for treating a metabolic pathway of heart tissue (i.e., Fatty Acids) and specifically fatty acid beta-oxidation and energy production (i.e., a even chain fatty acid metabolic pathway). For example, the present invention provides a treatment for severe neonatal translocase deficiency identified in Example 1 using triheptanoin-supplemented low fat formula (e.g., see [0089]). Neonatal translocase deficiency is a deficiency in carnitine-acylcarnitine translocase (CACT) an inner mitochondrial membrane enzyme that mediates the transport long chain fatty acid acylcarnitines into the mitochondria and exports free carnitine to the cytosol and is essential to fatty acid beta-oxidation and energy production in the mitochondria.

As such, the specification satisfies 35 U.S.C. § 112; regardless, the claims have been amended to expiate prosecution. For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 112.

Claim Rejections – Claims 26-32 are rejected under 35 U.S.C. 112 Second paragraph.

The Action rejects claims 26-32 under 35 U.S.C. 112 Second paragraph. Specifically, stating that the claims recite one or more doses and is therefore indefinite. Applicant respectfully submits that the claims are not indefinite as the skilled artisan will clearly know and/or can easily determine the number of doses.

In addition, it is not necessary for the application to state specifically what the exact amount to be administered to each and every patient, as that is within the scope of the knowledge of the skilled artisan. Since a statement of utility in the specification contains within it a connotation of how to use the present invention and the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied, e.g., see *In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also *In re Brana,* 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993). Specifically, it is not necessary to specify the dosage or how relief may be measured as it is known to one skilled in the art and such information can be obtained without undue experimentation. One skilled in the art, based on knowledge of compounds and treatments having similar physiological or biological activity, would be able to discern an appropriate dosage or how relief may be measured without undue experimentation, and as such is sufficient to satisfy 35 U.S.C. 112. Therefore, Applicant submits that the claims are not indefinite. For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 112.

Claim Rejections – Claims 42-46 are rejected under 35 U.S.C. 112 Second paragraph.

The Action rejects claims 21, 42-46, 47 and 55-57 under 35 U.S.C. 112 Second paragraph. The claims have been amended and as such fully comply with 35 U.S.C. 112 Second paragraph. For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 112.

Claims 17, 19-47 and 49-57 stand provisionally rejected under the nonstatutory, judicially created doctrine of double patenting over claims 25-27, 37-40, 42-45 and 47-56 of U. S. Patent Application No.10/371,385.

The Examiner states the subject matter claimed in the instant application is fully disclosed in the patent application since the patent and the application are claiming common subject matter. A terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed upon notice of allowable claims in either application to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting patent applications are shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claims 17, 19-47 and 49-57 stand provisionally rejected under the nonstatutory, judicially created doctrine of double patenting over claims 15-18 and 21-36 of U. S. Patent Application No.10/748,732.

It is unclear how application 10/748,732 entitled, "Access Circuit and Method for Allowing External Test Voltage to be Applied to Isolated Wells" has to do with the present invention. Specifically, claims 5 and 15 listed below. For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection.

> 15. The access circuit of claim 5 wherein the second control circuit comprises:
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> a shunt transistor having a gate terminal and a pair of source-drain terminals coupled between the externally accessible terminal and the gate electrode of the second transistor; and
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> a control transistor having a gate terminal coupled to receive the second access signal, the control transistor having a pair of source-drain terminals coupled between the externally accessible terminal and the gate terminal of the shunt transistor.

Conclusion

In light of the remarks and arguments presented above, Applicant respectfully submits that claims 17, 19-47 and 49-57 are pending in this application and claims 18 and 48 have been cancelled. Applicant submits that this application are in condition for allowance. Favorable consideration and allowance of the pending claims are therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: November 19, 2007.

Respectfully submitted,

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